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|------------------------------------|--------------------------|---------------------------------------|-------------------------|------------------|--|
| APPLICATION NO.                    | FILING DATE              | FIRST NAMED INVENTOR                  | ATTORNEY DOCKET NO.     | CONFIRMATION NO. |  |
| 09/380,695                         | 03/29/2002               | Dirk Gerrit Meuleman                  | 0/97263 US              | 5130             |  |
| 75                                 | 90 07/30/2002            | i i                                   | ·                       |                  |  |
|                                    | William M Blackstone     |                                       |                         | EXAMINER         |  |
| Akzo NOvel 1300 Piccard Drive #206 |                          |                                       | BAHAR, MOJDEH           |                  |  |
| Rockville, MD                      | Rockville, MD 20850-4373 |                                       | ART UNIT                | PAPER NUMBER     |  |
| Į.                                 |                          | )                                     | 1617                    |                  |  |
| *                                  |                          | , , , , , , , , , , , , , , , , , , , | DATE MAILED: 07/30/2002 | . 11             |  |

Please find below and/or attached an Office communication concerning this application or proceeding.

| ·   |   | Application No.               | Applicant(s)    |  |  |  |  |
|---|---|-------------------------------|-----------------|--|--|--|--|
| Offic Action Summary  |   |                               |                 |  |  |  |  |
|   |   | 09/380,695                    | MEULEMAN ET AL. |  |  |  |  |
|   |   | Examiner                      | Art Unit        |  |  |  |  |
|   | The HALLING DATE of this assume in the  | Mojdeh Bahar                  | 1617            |  |  |  |  |
| The MAILING DATE of this communication appears on the cover sheet with the carrespondence address Period for Reply  |   |                               |                 |  |  |  |  |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). |   |                               |                 |  |  |  |  |
| 1)  | Responsive to communication(s) filed on   |                               |                 |  |  |  |  |
| 2a)□  |   | — ·<br>s action is non-final. |                 |  |  |  |  |
| 3)  | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is |                               |                 |  |  |  |  |
| closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. <b>Disposition of Claims</b>  |   |                               |                 |  |  |  |  |
| 4)⊠ Claim(s) <u>1-4 and 6</u> is/are pending in the application.  |   |                               |                 |  |  |  |  |
| 4a) Of the above claim(s) is/are withdrawn from consideration.  |   |                               |                 |  |  |  |  |
| 5)  | Claim(s) is/are allowed.  |                               |                 |  |  |  |  |
| 6)⊠ Claim(s) <u>1-4 and 6</u> is/are rejected.  |   |                               |                 |  |  |  |  |
| 7)  | 7) Claim(s) is/are objected to.   |                               |                 |  |  |  |  |
| 8) Claim(s) are subject to restriction and/or election requirement.   |   |                               |                 |  |  |  |  |
| Application Papers  |   |                               |                 |  |  |  |  |
| 9) The specification is objected to by the Examiner.  |   |                               |                 |  |  |  |  |
| 10) ☐ The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  |   |                               |                 |  |  |  |  |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).   |   |                               |                 |  |  |  |  |
| 11) ☐ The proposed drawing correction filed on is: a) ☐ approved b) ☐ disapproved by the Examiner.  |   |                               |                 |  |  |  |  |
| If approved, corrected drawings are required in reply to this Office action.  |   |                               |                 |  |  |  |  |
| 12) The oath or declaration is objected to by the Examiner.   |   |                               |                 |  |  |  |  |
| Priority under 35 U.S.C. §§ 119 and 120   |   |                               |                 |  |  |  |  |
| 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).   |   |                               |                 |  |  |  |  |
| a) ☑ All b) ☐ Some * c) ☐ None of:  |   |                               |                 |  |  |  |  |
|   | 1. Certified copies of the priority documents have been received.   |                               |                 |  |  |  |  |
|   | 2. Certified copies of the priority documents have been received in Application No                              |                               |                 |  |  |  |  |
| <ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>   |   |                               |                 |  |  |  |  |
| 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  |   |                               |                 |  |  |  |  |
| a) ☐ The translation of the foreign language provisional application has been received.  15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.  |   |                               |                 |  |  |  |  |
| Attachment  |   |                               |                 |  |  |  |  |
| 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6  S Reterl and Trademed Office.  |   |                               |                 |  |  |  |  |

Application/Control Number: 09/380,695

Art Unit: 1617

## **DETAILED ACTION**

## Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Haenggi et al. in view of Berglund.

Haenggi et al. teaches a method of decreasing Lipoprotein (a) by administering 7.alpha.-Methyl-17.alpha.-ethynyl-17.beta.-hydroxy-5(10)-estren-3-one, hereinafterTibolone, to a human subject, see abstract in particular. Haenggi further teaches that Lp (a) has been shown to be a strong risk factor for coronary heart disease, see abstract.

Haenggi et al. does not particularly teach that employment of Tibolone in a method of inhibiting atherosclerosis.

Berglund teaches that Lp(a) has been implicated with an increased risk of atherosclerosis, see abstract.

Application/Control Number: 09/380,695

Art Unit: 1617

Page 3

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ Tiibolone in a method of inhibiting atherosclerosis.

One of ordinary skill in the art would have been motivated to employ Tibolone in a method of inhibiting atherosclerosis because Lp(a) has been implicated with an increased risk of atherosclerosis, and Tibolone is known to decrease Lp (a) levels thereby inhibiting atherosclerosis.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie, J.D., can be reached on (703) 308-4612. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar Patent Examiner July 25, 2002

RUSSELL TRAVERS PRIMARY EXAMINER GROUP 1200